MAR 3 1 2003

510K) Summary of Safety and Effectiveness

Date Prepared: January 23, 2003

Submitter Name: JOMED AG

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Device Trade Name: JOSTENT® SelfX

Device Common Name: Biliary Stent

Device Classification Name and Class: Biliary Catheter; Class II

Predicate Devices: Guidant DYNALINK™ Biliary Self Expanding Stent System (K002143)
Guidant OTW MEGALINK™ SDS Biliary Stent System (K001222)
Peripheral AVE Biliary Stent System (K983008)
Cordis Long Medium PALMAZ-SCHATZ Balloon Expandable Stent (K964688)

Device Description:

The JOSTENT SelfX Biliary Stent consists of a self-expanding Nitinol stent mounted on a catheter delivery system. The stent will be available in lengths of 44 and 68 mm and diameters of 6, 8, and 10 mm. The delivery system has a usable length of 75 cm and is compatible with 0.035" diameter guidewires and 7F introducers.

Intended Use:

The JOSTENT SelfX is intended for use in the palliation of malignant strictures in the biliary tree.

510(k) Summary (cont'd)

Device Technological Characteristics and Comparison to Predicate Device:

The JOSTENT SelfX is constrained within an outer catheter and is deployed in the biliary tree by retracting the outer catheter until the stent is unconstrained.

The stent material is substantially equivalent to currently marketed Nitinol Biliary stents and the catheter materials are substantially equivalent to currently marketed stent delivery systems and PTA catheters.

The range of device lengths and diameters are equivalent to currently marketed Biliary stent/catheter systems.

Performance Data:

The safety and effectiveness of the JOSTENT SelfX has been demonstrated through the data collected in bench and biocompatibility testing.

Conclusion:

The JOSTENT SelfX is substantially equivalent to the claimed predicate devices and other currently marketed biliary stent systems.

K030053
Premarket Notification [510(k)] Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

MAR 3 1 2003

Ms. Terry Schultz
Regulatory Affairs Manager
JOMED Inc.
15330 Avenue of Science, Suite 200
SAN DIEGO CA 92128

Re: K030053
Trade/Device Name: JOSTENT® SelfX Biliary Stent
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: March 21, 2003
Received: March 24, 2003

Dear Ms. Schultz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Daniel Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030053

Device Name: JOSTENT® SelfX Biliary Stent

FDA's Statement of the Indications for Use for device:

The JOSTENT SelfX Biliary Stent is intended for use in the palliation of malignant strictues in the biliary tree.

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal
and Radiological Devices
510(k) Number K030053